

2. Assembly

OSU331 ORCA Single Use 23L 2°C to 8°C



| | Component | Quantity |
|---|----------------------------|----------|
| A | Lid VIP Panel | 1 |
| B | PCM Cassettes | 6 |
| C | Payload Area | 1 |
| D | ORCA Single Use 23L System | 1 |

2.1 Conditioning

- 2.1.1 Place the ORCA Single Use 23L cassettes in a freezer with a warmest temperature of -18°C and coldest temperature of -30°C for 48 hours.
- 2.1.2 Spread the cassettes across a shelf with plenty of airflow to provide uniform, quick freezing of the PCM. Stacking the cassettes may result in inadequate freezing of the PCM and will take longer to become fully solid.
- 2.1.3 Before using, ensure the PCM cassettes are solid throughout, by gently pressing the cassette. If not solid, then continue to freeze until the PCM is frozen. Once suitably frozen, the PCM cassettes can be stored in the freezer until required for conditioning.

For Freezer to Fridge Conditioning

- 2.1.4 To prepare the PCM cassettes for packing remove them from the freezer and place in a refrigerated environment of 3.0°C (+0.5°C/-1.0°C) for a minimum of 2 hours. The PCM cassettes can be stored in this environment until required for packing. If the PCM cassettes experience a temperature greater than 4°C, we recommend restarting conditioning from 2.1.1.
- 2.1.5 The ideal temperature for the PCM cassettes when packing the system is 3°C+/- 0.5°C. If the temperature is above 4°C the performance will suffer, if the temperature is below 2°C then there is a risk of cold shocking the payload.

For Freezer to Ambient Conditioning

- 2.1.6 The ideal temperature for the PCM cassettes when packing the system is 4.5°C. If the temperature is above 5.5°C the performance will suffer, if the temperature is below 4.0°C then there is a risk of cold shocking the payload.
- 2.1.7 The cassettes have an aperture to check the surface temperature of the PCM brick (see image below). This will allow the user to assess the temperature of the PCM before packing when conditioning the cassettes.
- 2.1.8 Intelsius recommend that customers conduct validation work of the preparation guidelines based on equipment, processes and ambient environment in line with Good Distribution Practices. Section 2.1.4, 2.1.5, 2.1.6 and 2.1.7 do not need to be followed if the suggested conditioning timings have been validated.



Figure: The check coolant temperature aperture on each PCM cassette.

2.2 Packing Instructions

- 2.2.1 Pack the ORCA Single Use 23L system (D) with the front of the case facing you.
- 2.2.2 Place one PCM Cassette in the base of the ORCA Single Use 23L System (D), with the coloured side running left to right (Bi).
- 2.2.3 Pack two PCM cassettes, one at the front and one at the back, with the shortest side resting on the base of the VIP panel and the coloured sides running vertically (Bii).
- 2.2.4 Pack a further two PCM Cassettes against the sides of the ORCA Single Use insulation, one on each side, with the longest side resting on the base cassette and the coloured sides running front to back (Biii).
- 2.2.5 The payload can now be inserted into the space defined by these 5 cassettes. Place the remaining PCM Cassette flat on top, this cassette should rest on the left and right cassettes with the coloured sides running left to right (Bi).
- 2.2.6 Replace the Lid VIP Panel (A) and close the outer carton lid. Secure the lid following the tape area marked with dotted lines. Your ORCA Single Use is now ready to be shipped.